

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

#### WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

## **MEMORANDUM**

DATE: 2/25/02

SUBJECT: Chlorpropham (CIPC) (018301) Acute, Chronic and Cancer Anticipated

Residues and Dietary Exposure Assessments for the Tolerance Reassessment

Eligibility Decision; DP Barcode D280798.

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and

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Dietary Exposure Science Advisory Council (DESAC)

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TO: Gary Mullins, CRM

Special Review and Reregistration Division

Acute, chronic and cancer dietary exposure assessments were performed to determine the dietary exposure estimates associated with the post-harvest use of chlorpropham on whole potatoes to support the tolerance reassessment eligibility decision. This risk assessment is an updated risk analysis that has been conducted for chlorpropham. Previous chronic and cancer dietary assessments were performed using tolerance level residues and estimated percent crop treated (HED Chapter of the RED for Chlorpropham, K. Whitby, 1/19/95). The current chronic and cancer dietary exposure assessments incorporated Pesticide Data Program monitoring data. The acute dietary assessment used tolerance level residues and assumed 100% crop treated.

**EPA Reviewer: Danette Drew, 2/25/02** 

STUDY TYPE: Chlorpropham Acute, Chronic and Cancer Anticipated Residues

and Dietary Exposure Assessments for the Tolerance

Reassessment Eligibility Decision

**ACTIVE INGREDIENT:** Chlorpropham

**SYNONYMS:** CIPC; Isopropyl m-chlorocarbanilate

**RESIDUE OF CONCERN:** Plants: Chlorpropham per se

Livestock: Chlorpropham plus 4-hydroxychlorpropham-O-sulfonic

acid (4-HSA)

A cancer dietary risk assessment should be performed using the

metabolite 3-chloroaniline for both plants and livestock

commodities.

## **Executive Summary**

Acute, chronic and cancer dietary exposure assessments were requested to determine the dietary exposure estimates associated with the post-harvest use of chlorpropham on whole potatoes to support the tolerance reassessment eligibility decision. Previous chronic and cancer dietary assessments were performed using tolerance level residues and percent crop treated (Tier 2) (HED Chapter of the RED for Chlorpropham, K. Whitby, 1/19/95).

A Tier 1 acute dietary risk assessment was conducted for chlorpropham use on potatoes using tolerance-level residues and 100% crop treated. Dietary risk estimates are provided for the population subgroup females 13-50 years old (the only population requiring an acute assessment). This assessment concludes that for all included commodities, the <u>acute dietary risk estimate is below the Agency's level of concern</u> (<100% aPAD¹) at the <u>95</u><sup>th</sup> percentile of exposure (4% of the aPAD) for females 13-50 years old.

A somewhat refined chronic dietary exposure assessment was performed using PDP (Pesticide Data Program) monitoring data for potatoes and milk and anticipated residues derived from feeding studies for other livestock commodities (Tier 2/3). This assessment also concludes that for all commodities, the <u>chronic risk estimates are below the</u>

<sup>&</sup>lt;sup>1</sup>aPAD/cPAD = acute/chronic Population Adjusted Dose = Acute or Chronic RfD FOPA Safety Factor

Agency's level of concern (<100% cPAD¹) for the general U.S. population (4% of the cPAD) and all population subgroups. The chronic dietary exposure estimate for most highly exposed population subgroup, children 1-6 years old, is 10% of the cPAD.

The cancer dietary exposure assessment was performed to estimate the risk from potential residues of the metabolite 3-chloroaniline (3-CA) associated with the use of chlorpropham on potatoes. The Metabolism Committee decided that since no data are available to assess the cancer potency of 3-CA, the risk estimate should be calculated using the Q<sub>1</sub>\* for the 4- chloroaniline (4-CA).

When using a highly "local milkshed" scenario, the cancer dietary risk estimate for the general U.S. population is  $2.0 \times 10^{-6}$ . The "local milkshed" scenario assumes that finite residues may be expected in milk and liver consumed by individuals living in a highly localized area where cattle may be fed processed potato waste from nearby potato processing plants.

When using a more realistic "typical" scenario, the cancer dietary risk estimate for the general U.S. population is  $1.3 \times 10^{-6}$ . The Agency's level of concern for lifetime cancer risk is generally  $1.0 \times 10^{-6}$ . The "typical" scenario assumes that no potato waste containing chlorpropham is fed to livestock. This typical scenario is more realistic than the local milkshed scenario since residues of 3-CA are not expected in milk (not found in livestock metabolism studies) and only a small amount of the population can be assumed to live in an area where local potato waste is fed to livestock.

The cancer dietary risk estimate may be overestimated based on the use of the cancer potency factor for 4-CA as a surrogate for 3-CA. Although chlorpropham was classified as Group E (no evidence of carcinogenicity), there was some concern for the potential carcinogenicity of the 3-CA metabolite based on its similar structure to 4-CA, which does have a cancer potency factor.

Substitution of aromatic amines such as aniline with chlorine in either the ortho or para (as in 4-CA) position relative to the amino group has been shown to result in greater carcinogenic potency than observed for the parent compound (Amdur *et. al.*, 1991). However, substitution in the meta position (as in 3-CA) is not likely to cause increased potency. Therefore, the use of the  $Q_1^*$  from a para substituted aniline (4-CA) to estimate cancer risk from a meta substituted aniline (3-CA) is expected to overestimate the risk.

## I. Introduction

Exposure to pesticides can potentially occur through food, water, residential and occupational means. Risk assessment incorporates both exposure and toxicity of a given pesticide. The risk is expressed as a percentage of a dose that could be expressed as a daily or a long term dose, to pose no unreasonable adverse effects. This is called the

population adjusted dose (PAD), and is expressed as %PAD. References are available on the EPA/pesticides web site which discuss the acute and chronic risk assessments in more detail: "Available Information on Assessing Exposure from Pesticides, A User's Guide", 6/21/2000, web link:

http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6, 8/20/99.

## II. Toxicological Information

On September 15, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base on chlorpropham, reassessed the toxicological endpoints for acute and chronic dietary as well as occupational/residential exposure risk assessments (HIARC Memorandum, HED Doc. No. 012911, 10/16/98). A summary of the toxicological dose and endpoints for chlorpropham for use in the dietary exposure assessments is presented in Table 1.

The FQPA Safety Factor Committee recommended that the FQPA safety factor be removed since: 1) the toxicology data base is complete; 2) there is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies; 3) a developmental neurotoxicity study is not required; 4) dietary (food) exposure estimates are partially refined (using reassessed tolerances, % CT, and interim tolerances for milk and meat) resulting in a more realistic estimate of dietary exposure; 5) quantifiable contamination of surface or ground water is not likely to result from this use; and 6) there are currently no registered residential uses of chlorpropham, therefore, this type of exposure to infants and children is not expected (FQPA Memorandum, HED DOC. NO. 013027, 12/17/98).

On July 20, 1994, the HED Cancer Peer Review Committee classified chlorpropham in Group E (evidence of non-carcinogenicity for humans). The classification was supported by the following evidence: 1) a lack of carcinogenic potential demonstrated in mice and 2) the increase in benign Leydig cell tumors in rats occurred only at a dose in excess of a maximum tolerated dose (CARC Memorandum, TXR# 0050076,10/11/94).

The Metabolism Committee determined that the tolerance expression for chlorpropham on potatoes should *not* include the 3-chloroaniline (3-CA) compound, but that the dietary risk assessment for cancer should include this metabolite. The Metabolism Committee decided that since no data are available to assess the cancer potency of 3-CA, the risk estimate should be calculated using the  $Q_1^*$  for the 4- chloroaniline (4-CA) isomer. The Committee recognized that while this approach may overestimate the risk associated with 3-CA, it is still appropriate as no information is available to suggest that 3-CA is any less carcinogenic than 4-CA (D. Miller, 6/1/94).

Table 1. Summary of Toxicological Dose and Endpoints for Chlorpropham for Use in Dietary

## **Exposure Assessment**

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY		
Acute Dietary  (Females 13-50 years old)	NOAEL= 250 UF = 100 FQPA SF =1	Increased resorption and post-implantation loss	Developmental Toxicity-Rat		
y curs oray		Acute RfD = $2.5 \text{ mg/kg}$ aPAD <sup>1</sup> = $2.5 \text{ mg/kg}$			
Acute Dietary (General Population including Infants and Children)	None	An appropriate endpoint attributable to a single exposure was not available from the database including the developmental toxicity studies; the maternal endpoints are not attributable to single exposure. This risk assessment is NOT required.			
Chronic Dietary	NOAEL = 5	Thyroid effects Chronic Tox Dog			
(All Populations)	UF = 100 FQPA SF =1	Chronic RfD = $0.05 \text{ mg/kg/day}$ $cPAD^2 = 0.05 \text{ mg/kg/day}$			
Cancer (General Population)		$Q_1^{*3} = 6.38 \times 10^{-2} (mg/kg/day)^{-1}$	Q* for 4-CA used to assess potential dietary exposure risk from 3-CA on potatoes.		

1. 
$$\mathbf{aPAD} = \underline{\mathbf{acute RfD}}$$
 FQPA SF

2. 
$$\mathbf{cPAD} = \frac{\mathbf{chronic} \ \mathbf{RfD}}{\mathbf{FQPA} \ \mathbf{SF}}$$

3. Surrogate Q\* for 4-CA used to assess potential dietary exposure risk from 3-CA on potatoes.

# **III.** Residue Information

# Chlorpropham Use:

Chlorpropham (isopropyl *m*-chlorocarbanilate or CIPC) is a plant growth regulator used to inhibit sprout formation on stored potatoes.

The HED Metabolism Committee has determined that the residue to be included in the tolerance expression for stored potato is chlorpropham *per se*, and that the residues to be regulated in the tolerance expression for ruminant and hog commodities are chlorpropham and 4-hydroxychlorpropham-O-sulfonic acid (4-HSA) (Memo of 4/16/93, J. Abbotts, No Barcode and Memo of 12/17/93, J. Abbotts, No Barcode).

The metabolite 3-chloroaniline (3-CA) should be considered in the cancer dietary risk assessment but does not need to be included in the tolerance expression (MARC Memo, D. Miller, 6/1/94). The Metabolism Committee decided that since no data are available to assess the cancer potency of 3-CA, the risk estimate should be calculated using the  $Q_1^*$  for the 4- chloroaniline (4-CA) isomer. The Committee recognized that while this approach may overestimate the risk associated with 3-CA, it is still appropriate as no information is available to suggest that 3-CA is any less carcinogenic than 4-CA.

The current tolerances for the raw agricultural commodities listed in 40 CFR 180.181 for residues of chlorpropham and its 1-hydroxy-2-propyl-3'-chlorocarbanilate metabolite are established at 50 ppm in or on potatoes. The tolerance for residues on potatoes should be reduced to 30 ppm and be expressed in terms of chlorpropham *per se*.

Interim tolerances have been established for residues of chlorpropham in or on plant and animal commodities in CFR 180.319: these interim tolerances include 0.3 ppm on spinach and 0.05 ppm in milk; meat, fat, and meat byproducts of cattle, hog, horse, and sheep. The interim tolerance for spinach should be revoked. Based on the results of a ruminant feeding study, the interim tolerance for milk should be revoked and a tolerance for the combined residues of chlorpropham and 4-HSA (4-hydroxychlorpropham-O-sulfonic acid) in milk should be established at 0.30 ppm under 40 CFR 180.181. Similarly, the interim tolerances for residues of chlorpropham in meat, fat, and meat byproducts of cattle, goat, hog, horse, and sheep should be revoked. Tolerances for the combined residues of chlorpropham and 4-HSA in livestock tissues should be established under 40 CFR 180.181 for the meat of cattle, goat, horse, sheep and hog at 0.06 ppm (method limit of quantitation), at 0.06 ppm for meat byproducts, except kidney, at 0.30 for kidney, and at 0.20 ppm for fat.

## Acute Assessment:

Tolerance- level residues and 100% percent crop treated were used in the acute dietary assessment.

## Chronic Assessment:

Residues of chlorpropham *per se* from USDA Pesticide Data Program (PDP) monitoring data, calculated as point estimates, were used for potatoes in the chronic dietary assessment. Anticipated residues of parent chlorpropham and the 4-HSA metabolite in livestock tissues were derived from the ruminant feeding studies and were used as point estimates in the assessment. Total residues of chlorpropham and the metabolite 4-HSA in milk were calculated by determining the ratio of residues of parent to metabolite in milk from the feeding study and applied to the amount of parent reported in milk in the PDP monitoring data (PDP reports parent only in milk).

## Cancer Assessment

PDP data were not available for the metabolite 3-chloroaniline (3-CA) in potatoes or milk. The ratio of residues of 3-CA to parent chlorpropham was determined from magnitude of the residue studies (performed at maximum application rates) on potatoes and processed potato commodities. That ratio was then applied to the anticipated residue of chlorpropham *per se* on potatoes from the PDP monitoring data to determine the amount of 3-CA that can be realistically expected in potatoes.

3-CA was not measured in the livestock feeding studies. In livestock metabolism studies, 3-CA was not detected in milk, meat, kidney or fat. 3-CA was detected in liver. Although no 3-CA was detected in milk, a cancer dietary exposure assessment was performed using ½ LOD (limit of detection) for milk as well as the 3-CA residue found in liver and potatoes. This exposure scenario reflects a very conservative assumption that finite residues may be expected in milk and liver consumed by individuals living in a "local milkshed' where cattle may be fed processed potato waste from nearby potato processing plants.

A second cancer dietary exposure assessment was performed using potatoes only and omitting milk and liver. This assessment reflects a more typical exposure scenario than that of the "local milkshed" and assumes that no potato waste containing chlorpropham is fed to livestock. This typical scenario is more realistic than the local milkshed scenario since residues of 3-CA are not expected in milk and only a small amount of the population can be assumed to live in an area where local potato waste are fed to livestock.

## Percent Crop Treated Information:

BEAD supplied a Quantitative Usage Analysis (QUA) for chlorpropham use (A. Gilbert, 4/24/01). According to the QUA, the percent range of total potato production treated with chlorpropham (1996 data) ranged from 37% to 59% (maximum estimate). An average 64% of potato samples monitored by PDP (1994, 1995, and 2000 data; total of 1769 samples) had detectable residues of chlorpropham. Since PDP results reflect actual crop treated percentages, and the number of PDP samples with detectable residues exceeds BEAD's maximum estimated % crop treated, an additional adjustment for % crop treated was not incorporated in the chronic dietary assessments.

## **Processing Information:**

Based on the results of potato processing studies (MRIDs 426566801, 42653801, 42653901), a processing factor of 0.34x was used for 3-CA in dry potato food forms and a factor of 1.7x was used for 3-CA in fried potatoes. A processing factor of 1x was used for chlorpropham in dry potato commodities. DEEM<sup>TM</sup> default concentration factors were used for all other food forms.

## **Residue Estimates:**

#### **Potatoes**

For the acute dietary exposure assessment, the reassessed tolerance level for residues of chlorpropham on potatoes (30 ppm) was used, and 100% crop treated was assumed (Tier 1).

For the chronic dietary exposure assessment, PDP monitoring data were available for residues of parent chlorpropham on potatoes (1994, 1995, 2000). Of 1769 samples analyzed, there were 1141 detects. A point estimate of 0.91 ppm, based on the average sample residue, was calculated for use in the chronic assessment.

For the cancer dietary exposure assessment, the ratio of residues of 3-chloroaniline (3-CA) to parent chlorpropham was determined from potato magnitude of the residue studies (MRIDs 426566801, 42653801, 42653901; performed at maximum application rates). Residues of 3-CA were detected on potatoes, on average, at 0.022x that of parent. Using the AR of 0.91 ppm for parent chlorpropham on potatoes, and the 0.022x scaling factor, anticipated residues of 3-CA on potatoes are 0.02 ppm.

#### Milk

For the acute dietary exposure assessment, the reassessed tolerance level for the combined residues of chlorpropham and 4-HSA in milk (0.30 ppm) was used and 100% crop treated was assumed (Tier 1).

PDP data were available (1996, 1997, 1998) for chlorpropham per se in milk. PDP did not

analyze for 4-HSA in milk. Of 1891 samples analyzed, one had detectable residues of chlorpropham at 0.002 ppm. A point estimate of 0.002 ppm, based on average sample residues of parent chlorpropham, was calculated for use in the chronic assessment.

In the ruminant feeding study (MRID 43884501; D222987, 7/9/99, D.Drew), the average residue of 4-HSA in milk was 64x that of parent chlorpropham. It follows that the anticipated residue of 4-HSA would be 64 times the chlorpropham AR of 0.002 ppm from the PDP data. Therefore, an anticipated residue of 0.13 ppm [(0.002 x 64) +0.002 =0.13] in milk for the *combined* residues of chlorpropham and 4-HSA was used in the chronic dietary assessment.

PDP data were not available for 3-CA in milk. 3-CA was not measured in the feeding studies. The metabolite 3-CA was analyzed for but *not detected* in milk in the metabolism studies (MRID 42112201) at up to 4.4x the theoretical dietary burden (TDB). A residue value of ½ the LOD (0.0015ppm) was used for milk in the "local milkshed" cancer dietary assessment. This exposure scenario reflects the conservative assumption that finite residues may be expected in milk consumed by individuals living in a "local milkshed" where cattle may be fed processed potato waste from nearby potato processing plants. A residue value of zero was used for milk in the "typical "cancer dietary assessment, which assumes that no potato waste containing chlorpropham is fed to livestock and is based on the results of the metabolism data in which 3-CA is not detected in milk at 4.4x TDB.

## Livestock Tissue

For the acute dietary exposure assessment, the reassessed tolerance levels for the combined residues of chlorpropham and 4-HSA in livestock meat, kidney, liver, and fat were used and 100% crop treated was assumed (Tier 1).

For the chronic dietary exposure assessment, anticipated residues were calculated for the combined residues of chlorpropham and 4-HSA in livestock tissue using a cattle feeding study (MRID 43884501) and a theoretical dietary burden based on the AR for potatoes (see Tables 2-5 below).

In livestock metabolism studies (MRIDs 42112201, 42130401), 3-CA was not detected in meat, kidney or fat at 4.4x the theoretical dietary burden. 3-CA was detected in liver at 0.021 ppm at a 4.4x feeding level. The residue value of 0.0048 ppm was used for liver in the cancer dietary assessment reflecting the "local milkshed" scenario. Residue values of zero were used for livestock meat, kidney, and fat. For the "typical" scenario dietary assessment, zero residues were used for meat, kidney, fat, and liver.

Table 2. Dietary Burden for Use in Calculating Anticipated Residues in Cattle

II T 1	Andiduct and Desides and all	C 44
Feed	I Anticipated Residue, ppm <sup>1</sup> I	Cattle

		% of Diet <sup>2</sup>	% Dry Matter <sup>2</sup>	TDB <sup>3</sup> , ppm
Processed Potato Waste (wet peel)	2.7	40	15	7.2

 $<sup>^{1}</sup>$  AR processed potato waste calculated as chronic AR for whole potatoes [from PDP] times processing factor of 3x[from MRID44534501] for processed potato waste (0.91 x 3= 2.7)  $^{2}$ As per Table 1 of OPPTS GLN 860.1000.  $^{3}$ TDB(theoretical dietary burden)= AR (ppm)x % of diet÷ % dry matter

Table 3. Dietary Burden for Use in Calculating Anticipated Residues in Hog

E. d	Anticipated Residue,	Hog		
Feed	ppm <sup>1</sup>	% of Diet <sup>2</sup>	TDB <sup>3</sup> , ppm	
Culls	0.91	50	0.45	

<sup>&</sup>lt;sup>1</sup> AR culls = chronic AR for whole potatoes [from PDP] <sup>2</sup>As per Table 1 of OPPTS GLN 860.1000.

Table 4a. Anticipated Residues in Livestock Tissue (290 ppm Feeding Study)

Tissue	Residue at 290 ppm (40x for Beef; 640x for Hog) [ppm]	Residue Calculated at 1x TDB for Beef Cattle [ppm]	Residue Calculated at 1x TDB for Hog [ppm]
Meat	0.06	0.0015	0.000094
Kidney	0.31	0.0078	0.00048
Liver	0.065	0.0016	0.00010
Fat	0.17	0.0042	0.00026

Table 4b.Anticipated Residues in Livestock Tissue (870 ppm Feeding Study)

Tissue	Residue at 870 ppm (120x for Beef; 1900x for Hog) [ppm]	Residue Calculated at 1x TDB for Beef Cattle [ppm]	Residue Calculated at 1x TDB for Hog [ppm]
Meat	0.06	0.00050	0.000032
Kidney	1.46	0.012	0.00077
Liver	0.061	0.00051	0.000032
Fat	1.02	0.0085	0.00054

Table 4c. Residues in Livestock Tissue (2900 ppm Feeding Study)

<sup>&</sup>lt;sup>3</sup>TDB(theoretical dietary burden)= AR (ppm)x % of diet

## [D280798] [Chlorpropham/018301]

Tissue	Residue at 2900 ppm (400x for Beef; 6400x for Hog) [ppm]	Residue Calculated at 1x TDB for Beef Cattle [ppm]	Residue Calculated at 1x TDB for Hog [ppm]
Meat	0.098	0.00024	0.000015
Kidney	2.84	0.0071	0.00044
Liver	0.082	0.00020	0.000013
Fat	1.34	0.0034	0.00021

**Table 5.** *Chronic* **Anticipated Residues of CIPC and 4-HSA in Livestock Tissues** (average of residues calculated at 1x TBD from all three feeding levels)

Tissue	Beef Cattle Ave Residue [ppm]	Hog Ave Residue [ppm]
Meat	0.00075	0.000047
Kidney	0.0090	0.00056
Liver	0.00077	0.000048
Fat	0.0054	0.00034

Table 6. Summary of Residue Data and Anticipated Residues Used in Chlorpropham Dietary Analyses

## [D280798] [Chlorpropham/018301]

## Dietary exposure assessment / 11

D. C.	Data	No. of	No. of	Range of	Range LOD <sup>2</sup>	Processing	A		AR) Estimates/Tolerance
RAC	Source	Samples	Detectable Residues	detects <sup>1</sup> (ppm)	(1/2 wtd LOD) (ppm)	Factors	Acute (Tolerance)	Chronic (AR)	Cancer (AR)
Potato	PDP (1994, 1995, 2000)  (also MRIDs 42566801, 42653601, 42653701, 42653801, 42653901 42660201)	1769	1141	0.01-19	0.008- 0.047 (0.01)	granules/ flakes: 1x (0.34x for 3-CA) chips: 1x (1.7x for 3-CA)	30	0.91	0.020
Milk	PDP (1996, 1997, 1998) (Also MRIDs 43884501, 42112201)	1891	1	0.002	0.001- 0.005 (0.002)	-	0.30	0.13	0.0015 [Local Milkshed] No expectation of residue [Typical]
Liver <sup>3</sup>	MRIDs 43884501, 42112201, 42130401	9	6	0.06-0.072	0.06	-	0.06	0.00077 (0.000048)	0.0048 [Local Milkshed] No expectation of residue [Typical]
Kidney <sup>3</sup>	MRIDs 43884501, 42112201	9	9	0.19-3.4	0.06	-	0.30	0.0090 (0.00056)	No expectation of residue.
Meat <sup>3</sup>	MRIDs 43884501, 42112201	9	4	0.06-0.16	0.06	-	0.06	0.00075 (0.000047)	No expectation of residue.
Fat <sup>3</sup>	MRIDs 43884501, 42112201	9	9	0.15-2.8	0.06	-	0.20	0.0054 (0.00034)	No expectation of residue.

<sup>1.</sup> Highest residues of combined CIPC and 4-HSA are from a 2900 ppm feeding level (400x TDB for cattle;6400x TDB hog)

# I. DEEM<sup>TM</sup> Program and Consumption Information

<sup>2.</sup> Limit of Quantitation (LOQ) for meat, kidney, liver, fat.

<sup>3.</sup> Values in parentheses are for corresponding hog tissue; all other values are for corresponding tissue of cattle, sheep, horse, goat. Where only one value appears, it applies to hog, sheep, cattle, horse and goat.

Chlorpropham acute and chronic (including cancer) dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>) software Version 7.73, which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

HED notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups from the general U.S. population which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, risks estimated for these population subgroups were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

## II. Results/Discussion

HED's level of concern is 100% of the PAD. That is, estimated exposures above this level are of concern, while estimated exposures at or below this level are not of concern. The DEEM analyses estimate the dietary exposure of the U.S. population and 26 population subgroups. The results reported in Table 7 are for females 13-50 years old since that was the only population subgroup requiring an acute dietary exposure assessment. The results reported in Table 8 are for the U.S. Population (total), all infants (<1 year old), children 1-6, children 7-12, females 13-50, males 13-19, males 20+, and seniors 55+. The results for the other population subgroups are not reported in Table 8. This is because the numbers of respondents in the other subgroups were not sufficient, and thus the exposure estimates for these subgroups contained higher levels of uncertainty. However, the respondents in these subgroups were also part of larger subgroups which are listed in Attachment V. For example, nursing and non-nursing infants are included in all infants. The subgroups which are broken down by region, season, and ethnicity are also not included.

## Results of Acute Dietary Exposure Analysis

Table 7. Results of Acute Dietary Exposure Analysis at the 95th Percentile of Exposure

Population Subgroup	aPAD (mg/kg/day)	Exposure (mg/kg/day)	% aPAD
Females 13-50 years old	2.5	0.092494	4

## Chronic Dietary Exposure Analysis

**Table 8. Results of Chronic Dietary Exposure Analysis** 

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.05	0.001741	4.0
All Infants (< 1 year)	0.05	0.001864	4.0
Children 1-6 years	0.05	0.004950	10
Children 7-12 years	0.05	0.003018	6.0
Females 13-50	0.05	0.001147	2.3
Males 13-19	0.05	0.002053	4.1
Males 20+ years	0.05	0.001192	2.4
Seniors 55+	0.05	0.001159	2.3

## Results of Cancer Dietary Exposure Analysis

#### Local Milkshed Scenario

HED's level of concern for cancer exposure is  $1 \times 10^{-6}$ . The lifetime risk of developing cancer from exposure to potential residues of 3-CA as a result of chlorpropham use on potatoes is determined for the U.S. population (total) only. The estimated exposure to 3-CA is 0.000031 mg/kg/day. Applying the  $Q_1^*$  of  $6.38 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$  to the exposure value results in a cancer risk estimate of  $2.0 \times 10^{-6}$ .

 Table 9. Results of Cancer Dietary Exposure Analysis [Local Milkshed Scenario]

Population Subgroup	Exposure (mg/kg/day)	Anticipated Cancer Risk
U.S. Population (total)	0.000031	2.0 x 10 <sup>-6</sup>

## Typical Scenario

HED's level of concern for cancer exposure is  $1 \times 10^{-6}$ . The lifetime risk of developing cancer from exposure to potential residues of 3-CA as a result of chlorpropham use on potatoes is determined for the U.S. population (total) only. The estimated exposure to 3-CA is 0.000020 mg/kg/day. Applying the  $Q_1^*$  of  $6.38 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$  to the exposure value results in a cancer risk estimate of  $1.3 \times 10^{-6}$ .

**Table 10. Results of Cancer Dietary Exposure Analysis** [Typical Scenario]

Population Subgroup	Exposure (mg/kg/day)	Anticipated Cancer Risk
U.S. Population (total)	0.000020	1.3 x 10-6

## III. Discussion of Uncertainties

## **Monitoring Data**

Residue data incorporated into the Tier 2/3 type assessment included monitoring data from USDA PDP for potatoes and milk. PDP analyzed for parent only and did not look for the metabolites 3-CA or 4-HSA which are included in the dietary assessment. Anticipated residues of 4-HSA in meat and milk were calculated based on feeding studies and 3-CA residues were derived from livestock metabolism studies and potato field trials.

## **Processing Factors**

Based on the results of potato processing studies a processing factor of 0.34x was used for 3-CA in dry potato food forms and a factor of 1.7x was used for 3-CA in fried potatoes. A processing factor of 1x was used for chlorpropham in dry potato commodities (chlorpropham does not concentrate in dried potatoes). DEEM<sup>TM</sup> default concentration factors were used for all other food forms. Use of factors from cooking studies, if available for potatoes or meat commodities, may reduce dietary risk estimates.

Since PDP analyzes unpeeled potatoes and some DEEM food forms for potatoes are peeled, it would refine the chlorpropham dietary exposure estimate to have data on peeled potatoes. Also, since most of the residue (70% of radioactivity) may be expected in the peel (Coxon, DT and A Filmer, 1985, *Pesticide Science* 16:355-63), using residues on unpeeled potatoes may reduce dietary risk estimates.

## **Cancer Assumptions**

Although no 3-CA was detected in milk, a cancer dietary exposure assessment was performed using ½ LOD (limit of detection) for milk as well as the 3-CA residue found in liver and potatoes. This exposure scenario reflects the conservative assumption that finite residues may be expected in milk and liver consumed by individuals living in a "local milkshed' where cattle may be fed processed potato waste from nearby potato processing plants and may overestimate the cancer dietary risk.

A second cancer dietary exposure assessment was performed using potatoes only and omitting milk and liver. This assessment reflects a more typical exposure scenario than that of the "local milkshed" and assumes that no potato waste containing chlorpropham is fed to livestock. This typical scenario is more realistic than the local milkshed scenario since residues of 3-CA are not expected in milk and only a small amount of the population can be assumed to live in an area where local potato waste are fed to livestock.

The cancer dietary risk may be overestimated based on the use of the cancer potency factor for 4-CA being used as a surrogate for 3-CA. Although chlorpropham was classified as Group E (no evidence of carcinogenicity), there was some concern for the potential carcinogenicity of the 3-CA metabolite based on structure activity compared to 4-CA, which does have a cancer potency factor.

Substitution of aromatic amines such as aniline with chlorine in either the ortho or para (as in 4-CA) position relative to the amino group has been shown to result in greater potency than observed for the parent compound (Amdur *et. al.*, 1991). However, substitution in the meta position (as in 3-CA) is not likely to cause increased potency. Therefore, the use of the  $Q_1^*$  from a para substituted aniline (4-CA) to estimate cancer risk from a meta substituted aniline (3-CA) is expected to overestimate the risk.

#### IV. Conclusions

A Tier 1 acute dietary risk assessment was conducted for chlorpropham use on potatoes using tolerance-level residues and 100% crop treated. Dietary risk estimates are provided the population subgroup females 13-50 years old (the only population requiring an acute assessment). This assessment concludes that for all included commodities, the acute <u>risk</u> estimate is below the Agency's level of concern (<100% aPAD) at the <u>95<sup>th</sup></u> exposure percentile (4% of the aPAD) for females 13-50 years old.

A somewhat refined chronic dietary exposure assessment was performed using PDP (Pesticide Data Program) monitoring data for potatoes and milk and anticipated residues derived from feeding studies for other livestock commodities (Tier 2/3). This assessment also concludes that for all commodities, the chronic risk estimates are below the Agency's level of concern (<100% cPAD) for the general U.S. population (4% of the cPAD) and all population subgroups. The chronic dietary exposure estimate for highest exposed population subgroup, children 1-6 years old, is 10% of the cPAD.

The cancer dietary exposure assessment was performed to estimate the exposure risk to potential residues of the metabolite 3-chloroaniline (3-CA) associated with the use of chlorpropham on potatoes. The Metabolism Committee decided that since no data are available to assess the cancer potency of 3-CA, the risk estimate should be calculated using the  $Q_1^*$  for the 4- chloroaniline (4-CA).

When using a highly conservative "local milkshed" scenario, the cancer dietary risk estimate for the general U.S. population is  $2.0 \times 10^{-6}$ . The "local milkshed" scenario assumes that finite residues may be expected in milk and liver consumed by individuals living in a highly localized area where cattle may be fed processed potato waste from nearby potato processing plants.

When using a more realistic "typical" scenario, the cancer dietary risk estimate for the general U.S. population is  $1.3 \times 10^{-6}$ . The Agency's level of concern for lifetime cancer risk is generally  $1.0 \times 10^{-6}$ . The "typical" scenario assumes that no potato waste containing chlorpropham is fed to livestock. This typical scenario is more realistic than the local milkshed scenario since residues of 3-CA are not expected in milk (not found in livestock metabolism studies) and only a small amount of the population can be assumed to live in an area where local potato waste is fed to livestock.

The cancer dietary risk may be overestimated based on the use of the cancer potency factor for 4-CA being used as a surrogate for 3-CA. Although chlorpropham was classified as Group E (no evidence of carcinogenicity), there was some concern for the potential carcinogenicity of the 3-CA metabolite based on structural similarity to 4-CA, which does have a cancer potency factor.

Substitution of aromatic amines such as aniline with chlorine in either the ortho or para (as in 4-CA) position relative to the amino group has been shown to result in greater carcinogenic potency than observed for the parent compound (Amdur *et. al.*, 1991). However, substitution in the meta position (as in 3-CA) is not likely to cause increased potency. Therefore, the use of the  $Q_1^*$  from a para substituted aniline (4-CA) to estimate cancer risk from a meta substituted aniline (3-CA) is expected to overestimate the risk.

Table 11. Summary of Dietary Exposure and Risk for Chlorpropham

	Acute D	ietary	Chronic Dietary		Cancer	Cancer
Population Subgroup**	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Risk (Local Milkshed)	Risk (Typical)
U.S. Population (total)			0.001741	4.0	2.0 x 10 <sup>-6</sup>	1.3 x10 <sup>-6</sup>
All Infants (< 1 year)	NIA	NA	0.001864	4.0		
Children 1-6 years	NA	NA NA	0.004950	10		
Children 7-12 years			0.003018	6.0		
Females 13-50	0.092494	4.0	0.001147	2.3	NA	NA
Males 13-19			0.002053	4.1		
Males 20+ years	NA	NA	0.001192	2.4		
Seniors 55+			0.001159	2.3		

## V. List of Attachments

Attachment I: Quantitative Usage Analysis

Attachment II: Residue Data for Acute Dietary Analysis

Attachment III: Acute Dietary Analysis Results

Attachment IV: Residue Data for Chronic Dietary Analysis

Attachment V: Chronic Dietary Analysis Results

Attachment VI: Residue Data for Cancer Dietary Analysis [Local Milkshed]

Attachment VII: Cancer Dietary Analysis Results [Local Milkshed]
Attachment VIII: Residue Data for Cancer Dietary Analysis [Typical]

Attachment IX: Cancer Dietary Analysis Results [Typical]

cc: List file, D.Drew, G.Mullins (SRRD), L. Richardson (CEB) RDI: ChemSAC (2/13/02); DESAC Reviewers L. Cheng and R. Griffin (2/25/02); C.Eiden (2/25/02)

#### ATTACHMENT I

[D280798] [Chlorpropham/018301]

#### Dietary exposure assessment / 19

ChemicalCase No.PC CodeDateAnalystChlorpropham027118301April 24, 2001Anthony J. Gilbert

## Quantitative Usage Analysis (QUA)

Chlorpropham is a carbamate-type herbicide used almost exclusively in post-harvest applications to potatoes in storage. Ginkgo and easter lillies also have an active registration, but data on these use sites are not available. This active ingredient had a wide range of historical usage on sites such as field crops, fruits and vegetables, however, these uses are no longer registered and the corresponding tolerances have been revoked.

For potatoes, this active ingredient is an effective sprout inhibitor and should be applied two weeks after entering the storage facility. Chlorpropham applied prior to two weeks will prevent proper suberization, which is the process that strengthens the protective outer layering, or skin, of the potato. The maximum amount of time a potato should remain in storage is between 4-6 months.

After the harvest, potatoes are either sent directly to storage operators, marketed to processors and/or to the fresh market through packers/shippers. It is common for processors, packers/shippers and storage operators to hold the produce and store it for future sale, typically distributing the product throughout the following five months after harvest.

The range of total U. S. potato production from 1996 to 1998 was between 42.3 and 44.4 billion pounds (NASS). The principal destinations for potatoes are the processing and fresh markets. In 1996, approximately 51% of the harvest went to the processed market, whereas 43% passed through packers and shippers before entering the fresh market. The remaining percentage went to a variety of uses including livestock feed and seed.

The percent range of total potato production for 1996 that was treated with chlorpropham is between 37-55%. Chlorpropham may be applied by processors, packers and shippers and storage operators. In some cases, the potatoes may be treated twice as the product passes from the storage operators to the packers and shippers or the processors.

Total chlorpropham use for potato storage operators in 1996 was approximately 1,903,000 lbs. of active ingredient. This chemical was applied at a rate of 0.0021 lbs. per cwt. with one to two applications per year. Chlorpropham was applied to about 49% of the potatoes stored with storage operators.

For processors, total chlorpropham use in 1996 was approximately 1,376,000 lbs. of active ingredient (a.i.). The chemical was applied at a rate of 0.0018 lbs. per cwt. with one to two applications per year. Chlorpropham was applied to about 30% of the potatoes stored with processors.

In 1996, approximately 1,177,000 lbs. of active ingredient was applied annually for packers/shippers at a rate of 0.0016 lbs. per cwt. with one to two applications per year. About 49% of the potatoes stored with packers and shippers were treated with chlorpropham.

## Chlorpropham Usage for Potatoes<sup>2</sup>

## **Storage Operators:**

Total Volume Handled # of Applications/ye (1,000 cwt.)	Rate per Application (Lbs./cwt.)	% CT	Lbs. a.i. applied/year (1,000)
--------------------------------------------------------	----------------------------------	------	--------------------------------

<sup>&</sup>lt;sup>2</sup>1996 data from Agricultural Chemical Usage: Postharvest Applications - Apples and Potatoes May1998

## [D280798] [Chlorpropham/018301]

## Dietary exposure assessment / 20

163,677	1.1	0.0021	49%	190.3

## **Processors:**

Total Volume Handled (1,000 cwt.)	# of Applications/year	Rate per Application (Lbs./cwt.)	% CT	Lbs. a.i. applied/year (1,000)
228,558	1.1	0.0018	30%	137.6

**Packers/Shippers:** 

Total Volume Handled (1,000 cwt.)	# of Applications/year	Rate per Application (Lbs./cwt.)	% CT	Lbs. a.i. applied/year (1,000)
129,112	1.2	0.0016	49%	117.7

**Sources:** 

Agricultural Chemical Usage: Postharvest Applications - Apples and Potatoes, May 1998. USDA National Agricultural Statistics Service (NASS).

Agricultural Statistics 2000, USDA National Agricultural Statistics Service.

USDA Office of Pest Management and Policy and Pesticide Impact Assessment Program website at <a href="http://ipmwww.ncsu.edu/opmppiap/subcrp.htm">http://ipmwww.ncsu.edu/opmppiap/subcrp.htm</a>.

EPA Reference Files System (REFS).

0.060000

1.000 1.000

Ver. 7.

## [D280798] [Chlorpropham/018301]

321

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## ATTACHMENT II: Residue Data for Acute Dietary Analysis

U.S. Environmental Protection Agency

DEEM Acute analysis for CIPC

Residue file name: C:\deem\cipc\cipcac.RS7

Analysis Date 02-07-2002 Residue file dated: 02-07-2002/11:50:55

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Reference dose (aRfD) = 2.5 mg/kg bw/day
Comment: acute (T1: Tolerance , 100%CT)

Beef-meat byproducts

Def Res Adj.Factors Food Crop Code Grp Food Name (mqq) #1 #2 1,000 207 1C Potatoes/white-whole 30.000000 1.000 208 1C Potatoes/white-unspecified 30.000000 1.000 1.000 209 1C Potatoes/white-peeled 30.000000 1.000 1.000 210 Potatoes/white-dry 30.000000 1.000 1C 1.000 211 1C Potatoes/white-peel only 30.000000 1.000 1.000 318 Milk-nonfat solids 0.300000 1.000 D 1.000 Milk-fat solids 319 D 0.300000 1.000 1.000 320 Milk sugar (lactose) 0.300000 1.000 D 1.000

322 Μ Beef-other organ meats 0.060000 1.000 1.000 323 Beef-dried 0.060000 1.920 1.000 M 324 Beef-fat w/o bones 0.200000 1.000 1.000 Beef-kidney 325 0.300000 1.000 1.000 M

Beef-liver 326 M 0.060000 1.000 1.000 Beef-lean (fat/free) w/o bones 327 M 0.060000 1.000 1.000 328 M Goat-meat byproducts 0.060000 1.000 1.000

329 Goat-other organ meats 0.060000 1.000 M 1.000 Goat-fat w/o bone 1.000 330 M 0.200000 1.000 331 Goat-kidney 0.300000 1.000 1.000

332 Goat-liver 0.060000 1.000 1.000 M 333 M Goat-lean (fat/free) w/o bone 0.060000 1.000 1.000 334 Horsemeat 0.060000 1.000 M 1.000 336 1.000 M Sheep-meat byproducts 0.060000 1.000

337 Sheep-other organ meats 1.000 0.060000 1.000 Μ 338 Sheep-fat w/o bone 0.200000 1.000 M 1.000 339 M Sheep-kidney 0.300000 1.000 1.000 340 Sheep-liver 0.060000 1.000 M 1.000

#### [Chlorpropham/018301] Sheep-lean (fat free) w/o bone 0.060000 341 1.000 1.000 Pork-meat byproducts 0.060000 1.000 1.000 342 M 343 M Pork-other organ meats 0.060000 1.000 1.000 344 M Pork-fat w/o bone 0.200000 1.000 1.000

Dietary exposure assessment / 22

0.060000

1.000 1.000

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(1989-92 da

345	M	Pork-kidney	0.300000	1.000	1.000
346	M	Pork-liver	0.060000	1.000	1.000
347	M	Pork-lean (fat free) w/o bone	0.060000	1.000	1.000
398	D	Milk-based water	0.300000	1.000	1.000
424	M	Veal-fat w/o bones	0.200000	1.000	1.000
425	M	Veal-lean (fat free) w/o bones	0.060000	1.000	1.000
426	M	Veal-kidney	0.300000	1.000	1.000
427	M	Veal-liver	0.060000	1.000	1.000
428	M	Veal-other organ meats	0.060000	1.000	1.000
429	M	Veal-dried	0.060000	1.920	1.000

## ATTACHMENT III: Acute Dietary Analysis Results

Veal-meat byproducts

U.S. Environmental Protection Agency DEEM ACUTE Analysis for CIPC Residue file: cipcac.RS7 Adjustment factor #2 NOT

used.

[D280798]

430 M

Analysis Date: 02-07-2002/12:06:04 Residue file dated: 02-07-2002/12:04:3

Daily totals for food and foodform consumption used. Run Comment: "acute (T1: Tolerance , 100%CT) [F13+]"

\_\_\_\_\_\_

Summary calculations (per capita):

95th Per	centile	99th Per	centile	99.9th Pe	ercent
Exposure	% aRfD	Exposure	% aRfD	Exposure	% aR:

[D280798] [Chlorpropham/018301]

Dietary exposure assessment / 23

Females 13-50 yrs:

0.092494

3.70 0.156830 6.27 0.268683

10

## ATTACHMENT IV: Residue Data for Chronic Dietary Analysis

U.S. Environmental Protection Agency

1989-92 da

Ver. 7.

 ${\tt DEEM \ Chronic \ analysis \ for \ CIPC}$ 

Adjust. #2 NOT us

Residue file: C:\deem\cipc\cipccr.RS7

Adjust. #2 NOT us

Analysis Date 02-07-2002

Residue file dated: 02-07-2002/12:02:25

Reference dose (RfD) = 0.05 mg/kg bw/day

Comment:chronic (PDP potato/AR m/m)

_					
Food	Crop		RESIDUE	Adj.Fa	ctors
Code	Grp	Food Name	(ppm)	#1	#2
207		Potatoes/white-whole	0.910000	1.000	1.000
208		Potatoes/white-unspecified	0.910000	1.000	1.000
209		Potatoes/white-peeled	0.910000	1.000	1.000
210		Potatoes/white-dry	0.910000	1.000	1.000
211		Potatoes/white-peel only	0.910000	1.000	1.000
318		Milk-nonfat solids	0.130000	1.000	1.000
319	D	Milk-fat solids	0.130000	1.000	1.000
320	D	Milk sugar (lactose)	0.130000	1.000	1.000
321	M	Beef-meat byproducts	0.000770	1.000	1.000
322	M	Beef-other organ meats	0.000770	1.000	1.000
323	M	Beef-dried	0.000750	1.920	1.000
324	M	Beef-fat w/o bones	0.005400	1.000	1.000
325	M	Beef-kidney	0.009000	1.000	1.000
326	M	Beef-liver	0.000770	1.000	1.000
327	M	Beef-lean (fat/free) w/o bones	0.000750	1.000	1.000
328	M	Goat-meat byproducts	0.000770	1.000	1.000
329	M	Goat-other organ meats	0.000770	1.000	1.000
330	M	Goat-fat w/o bone	0.005400	1.000	1.000
331	M	Goat-kidney	0.009000	1.000	1.000
332	M	Goat-liver	0.000770	1.000	1.000
333	M	Goat-lean (fat/free) w/o bone	0.000750	1.000	1.000
334	M	Horsemeat	0.000750	1.000	1.000
336	M	Sheep-meat byproducts	0.000770	1.000	1.000
337	M	Sheep-other organ meats	0.000770	1.000	1.000
338	M	Sheep-fat w/o bone	0.005400	1.000	1.000
339	M	Sheep-kidney	0.009000	1.000	1.000
340	M	Sheep-liver	0.000770	1.000	1.000
341		Sheep-lean (fat free) w/o bone	0.000750	1.000	1.000

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[D280798]	Dietary exposure assessment / 25				
[Chlorprophar	m/018301]				
342 M	Pork-meat byproducts	0.000048	1.000	1.000	
343 M	Pork-other organ meats	0.000048	1.000	1.000	
344 M	Pork-fat w/o bone	0.000340	1.000	1.000	
345 M	Pork-kidney	0.000560	1.000	1.000	
346 M	Pork-liver	0.000048	1.000	1.000	
347 M	Pork-lean (fat free) w/o bone	0.000047	1.000	1.000	
398 D	Milk-based water	0.130000	1.000	1.000	
424 M	Veal-fat w/o bones	0.005400	1.000	1.000	
425 M	Veal-lean (fat free) w/o bones	0.000750	1.000	1.000	
426 M	Veal-kidney	0.009000	1.000	1.000	
427 M	Veal-liver	0.000770	1.000	1.000	
428 M	Veal-other organ meats	0.000770	1.000	1.000	
429 M	Veal-dried	0.000750	1.920	1.000	
430 M	Veal-meat byproducts	0.000770	1.000	1.000	

# ATTACHMENT V: Chronic Dietary Analysis Results

U.S. Environmental Protection Agency DEEM Chronic analysis for CIPC	Ver. 7. (1989-92 data
Residue file name: C:\deem\cipc\cipccr.RS7 Analysis Date 02-07-2002/12:03:11 Residue Reference dose (RfD, Chronic) = .05 mg/kg bw/c COMMENT 1: chronic (PDP potato/AR m/m)	
Total exposure by populati	lon subgroup
	Total Exposure

Population Subgroup	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.001741	3.5%

[Chlorpropham/018301]	, <b>p</b>	
U.S. Population (spring season)	0.001692	3.4%
U.S. Population (summer season)	0.001634	3.3%
U.S. Population (autumn season)	0.001847	3.7%
U.S. Population (winter season)	0.001794	3.6%
Northeast region	0.001743	3.5%
Midwest region	0.001976	4.0%
Southern region	0.001596	3.2%
Western region	0.001705	3.4%
Hispanics	0.001635	3.3%
Non-hispanic whites	0.001760	3.5%
Non-hispanic blacks	0.001685	3.4%
Non-hisp/non-white/non-black	0.001781	3.6%
All infants (< 1 year)	0.001864	3.7%
Nursing infants	0.000448	0.9%
Non-nursing infants	0.002460	4.9%
Children 1-6 yrs	0.004950	9.9%
Children 7-12 yrs	0.003018	6.0%
Females 13-19 (not preg or nursing)	0.001553	3.1%
Females 20+ (not preg or nursing)	0.001057	2.1%
Females 13-50 yrs	0.001147	2.3%
Females 13+ (preg/not nursing)	0.001444	2.9%
Females 13+ (nursing)	0.001602	3.2%
Males 13-19 yrs	0.002053	4.1%
Males 20+ yrs	0.001192	2.4%
Seniors 55+	0.001159	2.3%
Pacific Region	0.001694	3.4%

Dietary exposure assessment / 26

[D280798]

#### ATTACHMENT VI: Residue Data for Cancer Dietary Analysis [Local Milkshed]

U.S. Environmental Protection Agency

DEEM Chronic analysis for CIPC 1989-92 da

Residue file: C:\deem\cipc\cipccan.RS7

Adjust. #2 NOT us

Ver. 7.

Analysis Date 02-13-2002 Residue file dated: 02-07-2002/12:22:34

 $Q^* = 0.0638$ 

Comment: 'local milkshed' w/ milk and liver [Ars for 3-CA (q\* for 4-CA)]

Food Crop RESIDUE Adj.Factors Code Grp Food Name (ppm) #1 #2 -----\_\_\_\_ \_\_\_\_ 207 1C Potatoes/white-whole 11-Uncooked 0.020000 1.000 1.000 12-Cooked: NFS 0.020000 1.000 1.000 13-Baked 0.020000 1.000 1.000 14-Boiled 0.020000 1.000 1.000 15-Fried 0.020000 1.700 1.000 31-Canned: NFS 0.020000 1.000 1.000 208 1C Potatoes/white-unspecified 31-Canned: NFS 1.000 1.000 0.020000 209 1C Potatoes/white-peeled 11-Uncooked 0.020000 1.000 1.000 12-Cooked: NFS 0.020000 1.000 1.000 13-Baked 0.020000 1.000 1.000 0.020000 1.000 1.000 14-Boiled 15-Fried 0.020000 1.700 1.000 31-Canned: NFS 0.020000 1.000 1.000 32-Canned: Cooked 0.020000 1.000 1.000 34-Canned: Boiled 0.020000 1.000 1.000 42-Frozen: Cooked 0.020000 1.000 1.000 43-Frozen: Baked 0.020000 1.000 1.000 45-Frozen: Fried 0.020000 1.000 1.000 210 1C Potatoes/white-dry 0.020000 0.340 1.000 211 1C Potatoes/white-peel only 13-Baked 0.020000 1.000 1.000 15-Fried 0.020000 1.700 1.000 318 D Milk-nonfat solids 0.001500 1.000 1.000 Milk-fat solids 319 D 0.001500 1.000 1.000

[D280798] [Chlorprophai	m/018301]	Dietary exposure assessment / 28		
320 D	Milk sugar (lactose)	0.001500	1.000	1.000
326 M	Beef-liver	0.004800	1.000	1.000
332 M	Goat-liver	0.004800	1.000	1.000
340 M	Sheep-liver	0.004800	1.000	1.000
346 M	Pork-liver	0.004800	1.000	1.000
398 D	Milk-based water	0.001500	1.000	1.000

ATTACHMENT VII: Cancer Dietary Analysis Results [Local Milkshed]

```
Ver. 7.
U.S. Environmental Protection Agency
                                                      (1989-92 data
DEEM Chronic analysis for CIPC
Residue file name: C:\deem\cipc\cipccan.RS7 Adjustment factor #2 NOT us
Analysis Date 02-13-2002/13:42:40 Residue file dated: 02-07-2002/12:22:3
Q* = 0.0638
COMMENT 1: 'local milkshed' w/ milk and liver [Ars for 3-CA (q* for 4-CA)]
______
                 Total exposure by population subgroup
                                            Total Exposure
        Population
                                      mg/kg
                                                 Lifetime risk
                                   body wt/day
         Subgroup
                                                 (Q*=.0638)
```

[D280798] [Chlorpropham/018301]	Dietary exposure assessment / 29	
U.S. Population (total)	0.000031	1.96E-06

#### ATTACHMENT VIII: Residue Data for Cancer Dietary Analysis [Typical]

U.S. Environmental Protection Agency

Ver. 7. 1989-92 da

DEEM Chronic analysis for CIPC

Residue file: C:\deem\cipc\cipccantyp.RS7

Adjust. #2 NOT us

Analysis Date 02-13-2002 Residue file dated: 02-07-2002/12:46:33

0\* = 0.0638

Comment: 'typical' w/ no milk/meat [Ars for 3-CA (q\* for 4-CA)]

RESIDUE Food Crop Adj.Factors (ppm) Code Grp Food Name #1 #2 ---- ----\_\_\_\_\_ \_\_\_\_\_ 207 1C Potatoes/white-whole 0.020000 11-Uncooked 1.000 1.000 0.020000 12-Cooked: NFS 1.000 1.000 13-Baked 0.020000 1.000 1.000 1.000 1.000 14-Boiled 0.020000 1.700 1.000 15-Fried 0.020000 31-Canned: NFS 0.020000 1.000 1.000 208 1C Potatoes/white-unspecified 31-Canned: NFS 0.020000 1.000 1.000 209 1C Potatoes/white-peeled 11-Uncooked 0.020000 1.000 1.000 12-Cooked: NFS 0.020000 1.000 1.000 13-Baked 0.020000 1.000 1.000 14-Boiled 0.020000 1.000 1.000 15-Fried 0.020000 1.700 1.000 31-Canned: NFS 0.020000 1.000 1.000 32-Canned: Cooked 0.020000 1.000 1.000 34-Canned: Boiled 0.020000 1.000 1.000 42-Frozen: Cooked 0.020000 1.000 1.000 43-Frozen: Baked 1.000 1.000 0.020000 45-Frozen: Fried 0.020000 1.000 1.000 210 1C Potatoes/white-dry 0.020000 0.340 1.000 211 1C Potatoes/white-peel only 13-Baked 0.020000 1.000 1.000 15-Fried 0.020000 1.700 1.000

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## ATTACHMENT IX: Cancer Dietary Analysis Results [Typical]

U.S. Environmental Protection Agency

DEEM Chronic analysis for CIPC

Residue file name: C:\deem\cipc\cipccantyp.RS7 Adjustment factor #2 NOT us Analysis Date 02-13-2002/13:44:08

Residue file dated: 02-07-2002/12:46:3

Q\* = 0.0638

COMMENT 1: 'typical' w/ no milk/meat [Ars for 3-CA (q\* for 4-CA)]

Total exposure by population subgroup

Total exposure by population subgroup

Total Exposure

Population

Subgroup

Mg/kg

Lifetime risk

body wt/day

(Q\*= .0638)

[D280798] [Chlorpropham/018301]	Dietary exposure assessment / 32	
U.S. Population (total)	0.000020	1.28E-06